

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

MARY ANN WARD,

Plaintiff,

v.

Civil Action No. 2:20-cv-00334

LiNA MEDICAL USA, INC. d/b/a
LiNA MEDICAL, LiNA MEDICAL ApS d/b/a
LiNA MEDICAL, LiNA MEDICAL POLSKA
SP. Z.O.O. d/b/a LiNA MEDICAL,
KEBOMED, A.G. d/b/a LiNA MEDICAL,
THE UNITED STATES OF AMERICA, and
RALEIGH GENERAL HOSPITAL, LLC,

Defendants.

MEMORANDUM OPINION AND ORDER

Pending are (1) defendant Raleigh General Hospital LLC's motion to dismiss plaintiff Mary Ann Ward's complaint, or in the alternative, motion for summary judgment, filed August 24, 2020 and (2) defendants Kebomed, A.G., LiNA Medical ApS, LiNA Medical Polska SP. Z.O.O., LiNA Medical USA, Inc.'s motion to dismiss, filed August 26, 2020. ECF Nos. 18, 20.

I. Background

This case involves a type of hysterectomy, the surgical removal of the uterus, achieved through a process known as "morcellation." The surgery at issue in this case involved

the use of a tool known as a "power morcellator," an electric device with fast-spinning blades that minces a uterus and fibroids (noncancerous growths on the uterus) into smaller pieces inside the abdominal cavity. Compl. ¶17, ECF No. 1. The mincing of uterine tissue allows a surgeon to remove the tissue through small incisions in the abdomen during laparoscopic surgery. Id. Morcellators were first marketed in 1995. Id.

A concern associated with power morcellators is that the shredding caused by their high-velocity spinning blades can in turn cause cellular particles to spread throughout the abdomen. Id. at ¶18. If undetected cancer cells are present in the tissue, this can cause cancer to spread throughout the body and upstage the cancer to a higher level. Id. As early as 1997, academics in the medical community began raising alarms that uterine morcellation could cause undetected cancer to spread. Id. (citing to six articles between 1997 and 2012). Over time, awareness of the cancer spread risk increased, and various actors within the medical community responded with warnings and recommended risk mitigation techniques. For example, in December 2013, the Society of Gynecologic Oncology (SGO) recommended that health care providers perform pre-operative cancer screenings, inform patients of risks, and not morcellate tissue in patients with possible cancer. Id. at ¶22.

A number of hospitals require morcellation to be performed inside a uterine containment bag to prevent tissue from spreading. Id. at ¶¶25, 27.

In April 2014, the U.S. Food and Drug Administration ("FDA") warned that 1 in 350 women who undergo morcellation for hysterectomies or myomectomies (the removal of fibroids) may have undiagnosed uterine cancer. Id. at ¶28. The FDA warned that the use of power morcellators may spread and upstage cancer, potentially from stage 1 to stage 4, and decrease long-term survival in patients. Id. The FDA discouraged the use of laparoscopic power morcellators in hysterectomies and recommended health care providers carefully weigh the risks associated with the procedure and discuss those risks with their patients. Id. at ¶29.

In May 2018, plaintiff Mary Ann Ward made the decision with her doctor, Dr. Juddson Lindley, to undergo a hysterectomy to deal with worsening bowel protrusions. Id. at ¶34. Dr. Lindley decided to perform the hysterectomy using a power morcellator but did not discuss the procedure or its risks with plaintiff. Id. at ¶35. Dr. Lindley did not perform a pre-operation endometrial biopsy to test plaintiff's uterine tissue for cancer. Id. at ¶36. The hysterectomy took place on May 16, 2018. Id. at ¶38.

A pathology report on May 22, 2018 revealed that plaintiff had cancer and Dr. Lindley notified plaintiff around that date that she had cancer. Id. at ¶40. Plaintiff visited Dr. Lindley in June 2018, accompanied by her granddaughter. Id. at ¶42. Plaintiff's granddaughter recorded the conversation between plaintiff and Dr. Lindley. Id. During that discussion, Dr. Lindley indicated that he "screwed up," "dropped the ball" and that the procedure was a "swing and a miss." Id. Dr. Lindley further conceded that he had failed to discuss the risk of morcellation or the nature of the procedure, that he should have conducted a biopsy prior to morcellation, and that he would not have performed the surgery had he known of the cancer. Id. Dr. Lindley then referred plaintiff to West Virginia University's medical facilities, where her cancer was diagnosed as "treatable, [but] not curable" and was directed to begin chemotherapy immediately. Id. at ¶43.

Plaintiff claims that the United States of America breached its duty of care to her as a patient, violating the Federal Torts Claim Act (Count I). The United States notified plaintiff in 2018 that Dr. Lindley was a federal employee, and that any claims against Dr. Lindley fall under the Federal Torts Claims Act, which is why the United States is a defendant to this case, id. at ¶10, though it is unclear from the complaint

the capacity in which Dr. Lindley was employed by the United States. Jurisdiction over this case primarily arises under 28 U.S.C. § 1346(b)(1), giving federal courts original jurisdiction over claims against the United States of America for money damages. Id. at ¶2. Subject matter jurisdiction over the additional counts is supplemental to Count I. See 28 U.S.C. §1367(a). The United States has not moved to dismiss the sole count against it.

Plaintiff also claims that defendant Raleigh General Hospital, LLC ("RGH") is liable for negligence (Count II). Id. at ¶¶55-63. Specifically, plaintiff contends that RGH owned the power morcellator and the surgery took place at Raleigh General Hospital and that RGH negligently failed to warn plaintiff and the general public of the cancer spreading risks of morcellation of which it knew or should have known, failed to ban the use of the power morcellator, and failed to equip the morcellator with an appropriate failsafe to ensure the machine did not spread and upstage cancer. Id. at ¶¶55-63. Subject matter jurisdiction over Count II is supplemental to Count I. See 28 U.S.C. §1367(a). RGH has moved to dismiss Count II.¹

¹ Count II was also initially brought against LifePoint Health, which was voluntarily dismissed with prejudice from the case on September 14, 2020. Voluntary Dismissal Order, ECF No. 26.

The power morcellator used in plaintiff's surgery was the Xcise model morcellator which was produced by Defendants LiNA Medical USA, Inc.; LiNA Medical ApS; LiNA Medical Polska SP. Z.O.O.; and Kebomed, AG, all doing business as LiNA Medical (collectively "LiNA"). Id. at ¶65. Plaintiff contends that LiNA knew or should have known of the cancer spreading risks associated with power morcellators and failed to respond appropriately to eliminate or mitigate those risks. Id. at ¶¶45-46. Plaintiff alleges that LiNA should have designed, marketed, and sold the product with a containment bag or other device designed to prevent the dissemination of cancerous tissue. Id. at ¶47. Plaintiff further contends that LiNA's failure to adequately recommend, require, or design a system that would prevent cancer spread resulted in plaintiff's bodily injury and reduction in life expectancy. Id. at ¶50.

Plaintiff brings seven causes of action against LiNA, contending that LiNA is liable in strict liability for failure to warn (Count III) and design defect (Count IV), as well as liable for a breach of the implied warranty of merchantability and fitness (Count V), negligence (Count VI), violation of the West Virginia Consumer Credit and Protection Act (Count VII), negligent misrepresentation (Count VIII), and fraudulent

concealment (Count IX). LiNA has moved to dismiss Counts III, IV, and V.

II. Legal Standard

Federal Rule of Civil Procedure 8(a)(2) requires that a pleading contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Rule 12(b)(6) correspondingly provides that a pleading may be dismissed when there is a "failure to state a claim upon which relief can be granted." To survive a motion to dismiss, a pleading must recite "enough facts to state a claim to relief that is plausible on its face." Giarratano v. Johnson, 521 F.3d 298, 302 (4th Cir. 2008) (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007)). In other words, the "[f]actual allegations must be enough to raise a right to relief above the speculative level." Twombly, 550 U.S. at 555 (citation omitted).

"In resolving a motion pursuant to Rule 12(b)(6)[,] a district court cannot consider matters outside the pleadings without converting the motion into one for summary judgment." Occupy Columbia, 738 F.3d at 116 (citing Fed. R. Civ. P. 12(d)). "A court may, however, consider a 'written instrument' attached as an exhibit to a pleading, 'as well as [documents] attached to

the motion to dismiss, so long as they are integral to the complaint and authentic.'" Id. (alteration in original) (internal citation omitted) (quoting Fed. R. Civ. P. 10(c) and Phillips v. Pitt Cty. Mem'l Hosp., 572 F.3d 176, 180 (4th Cir. 2009)).

A district court's evaluation of a motion to dismiss is underlain by two principles. First, the court "must accept as true all of the factual allegations contained in the [pleading]." Erickson v. Pardus, 551 U.S. 89, 94 (2007) (citing Twombly, 550 U.S. at 555-56). Such factual allegations should be distinguished from "mere conclusory statements," which are not to be regarded as true. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) ("[T]he tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions."). Second, the court must "draw[] all reasonable factual inferences . . . in the [nonmovant's] favor." Edwards v. City of Goldsboro, 178 F.3d 231, 244 (4th Cir. 1999).

Federal district courts are courts of limited subject-matter jurisdiction, possessing "only the jurisdiction authorized them by the United States Constitution and by federal statute." United States ex. rel. Vuyyuru v. Jadhav, 555 F.3d 337, 347 (4th Cir.2008). As such, "there is no presumption that the court has jurisdiction." Pinkley, Inc. v. City of

Frederick, 191 F.3d 394, 399 (4th Cir.1999) (citing Lehigh Mining & Mfg. Co. v. Kelly, 160 U.S. 327, 327 (1895)). Indeed, when the existence of subject-matter jurisdiction is challenged under Rule 12(b)(1), "[t]he plaintiff has the burden of proving that subject matter jurisdiction exists." Evans v. B.F. Perkins Co., 166 F.3d 642, 647 (4th Cir.1999); see also Richmond, Fredericksburg, & Potomac R.R. Co. v. United States, 945 F.2d 765, 768 (4th Cir.1991). If subject-matter jurisdiction is lacking, the claim must be dismissed. See Arbaugh v. Y & H Corp., 546 U.S. 500, 506 (2006).

Summary judgment is appropriate only "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "Material" facts are those necessary to establish the elements of a party's cause of action. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986); see also News & Observer Publ'g Co. v. Raleigh-Durham Airport Auth., 597 F.3d 570, 576 (4th Cir. 2010). A "genuine" dispute of material fact exists if, in viewing the record and all reasonable inferences drawn therefrom in a light most favorable to the non-moving party, a reasonable fact-finder could return a verdict for the non-moving party. Anderson, 477 U.S. at 248.

Inferences that are "drawn from the underlying facts . . . must be viewed in the light most favorable to the party opposing the motion." United States v. Diebold, Inc., 369 U.S. 654, 655 (1962). A party is entitled to summary judgment if the record, as a whole, could not lead a rational trier of fact to find for the non-moving party. Williams v. Griffin, 952 F.2d 820, 823 (4th Cir. 1991). Conversely, summary judgment is inappropriate if the evidence is sufficient for a reasonable fact-finder to return a verdict in favor of the non-moving party. Anderson, 477 U.S. at 248.

III. Discussion

A. Raleigh General Hospital's Motion to Dismiss

1. Failure to comply with the Medical Professional Liability Act

Raleigh General Hospital, named only in Count II-Negligence, contends that plaintiff failed to comply with the pre-suit requirements of the Medical Professional Liability Act (MPLA) and thus cannot proceed with a claim of negligence against it. In West Virginia, before a plaintiff may validly file a medical professional liability lawsuit against a health

care provider, she must comply with the MPLA's pre-suit notification requirements. W. Va. Code § 55-7B-6. The statute requires that "[a]t least thirty days prior to the filing of a medical professional liability action against a health care provider, the claimant shall serve by certified mail, return receipt requested, a notice of claim on each health care provider the claimant will join in litigation." Id. The notice of claim must include "a statement of the theory or theories of liability upon which a cause of action may be based, and a list of all health care providers and health care facilities to whom notices of claim are being sent, together with a screening certificate of merit." Id.

The screening certificate of merit – executed under oath by a health care provider who is qualified as an expert under the West Virginia rules of evidence – must state with particularity:

(1) The expert's familiarity with the applicable standard of care in issue; (2) the expert's qualifications; (3) the expert's opinion as to how the applicable standard of care was breached; and (4) the expert's opinion as to how the breach of the applicable standard of care resulted in injury or death.

Id. The pre-suit requirements of the MPLA are substantive law that apply in federal court. See e.g., Stanley v. United States, 321 F. Supp 2d 805 (N.D. W. Va. 2004); Gaylor v. Dagher, 2011 U.S. Dist. LEXIS 12400 (S.D. W. Va. Jan. 14, 2011); Motto

v. Corr. Med. Servs., 2007 U.S. Dist. LEXIS 72436 (S.D. W. Va. Sept. 27, 2007).

RGH argues that the plaintiff's screening certificate of merit, submitted by Dr. Jason S. James, M.D., did not state with particularity how the applicable standard of care was breached or how the breach of the standard of care resulted in injury. Dr. James provided a brief, one paragraph explanation of his opinion that:

Raleigh General Hospital's failures in establishing appropriate policies and procedures to ensure that the risks associated with morcellation were adequately explained to Mrs. Ward and its general failure to take appropriate and reasonable measures to protect Ms. Ward from the dangers and risks of morcellation constituted a breach of the standard of care and these deviations from the accepted standard of care proximately caused Mary Ann Ward to suffer injury and damages, including Mrs. Ward having to undergo chemotherapy.

Notice of Claim and Certificate of Merit, ECF No. 18-2 at 6.

Counsel for RGH subsequently wrote to plaintiff's counsel, laying out what it purported to be the certificate's deficiencies and requesting a second, more particularized certificate of merit. Letter to Bastress, ECF No. 18-3.

Plaintiff's counsel responded via letter that it viewed the certificate as sufficiently particularized under the statute and that plaintiff would not be providing a second, more particularized certificate of merit. Letter to Browning and Offutt, ECF No. 18-3.

RGH contends that its challenge to the sufficiency of the certificate of merit is a matter of subject matter jurisdiction to be brought under Federal Rule of Civil Procedure 12(b)(1), as opposed to a 12(b)(6) motion for failure to state a claim. For this proposition, RGH cites to State ex rel. PrimeCare Medical of West Virginia, Inc. v. Faircloth, in which the Supreme Court of Appeals of West Virginia describes the requirements of the MPLA as "jurisdictional" and held that failure to provide pre-suit notice deprived the state circuit court of subject matter jurisdiction. 835 S.E.2d 579, 585 (W.Va. 2019). However, the jurisdiction of federal district courts, even when sitting in diversity, is derived from the Constitution and acts of Congress, not decisions of the state courts. U.S. Const. art. III, §2, cl. 1. The court has jurisdiction over Count II because of the supplemental jurisdiction statute,² 28 U.S.C. § 1367(a), and only an act of Congress may divest that jurisdiction. In actuality, the core of what RGH argues in its motion is that the plaintiff has not met a requirement of a medical negligence claim under West Virginia substantive law, which goes to the merits of the claim and should be addressed under Federal Rule of Civil Procedure

² The anchor claim for supplemental jurisdiction here is Count I, which arises under 28 U.S.C. § 1346(b)(1), giving federal courts original jurisdiction over claims against the United States for money damages.

12(b)(6), not 12(b)(1). See Wright & Miller, 5B Federal Practice and Procedure § 1350 ("Nor, as many courts have noted, should a motion under Rule 12(b)(1) be confused with a motion under Rule 12(b)(6) to dismiss for failure to state a claim for relief under federal or state law because the two are analytically different."). The court thus construes RGH's arguments as arguments for dismissal under Rule 12(b)(6).

The Supreme Court of Appeals of West Virginia has instructed that challenges to a plaintiff's compliance with the MPLA's pre-suit requirements be reviewed in light of the two aims of the statute: "to prevent frivolous medical malpractice lawsuits and promote pre-suit resolution of non-frivolous medical malpractice claims, but not to restrict or deny citizens' access to the courts." Earle v. City of Huntington, 2016 WL 3198396, at *5 (S.D. W.Va. June 8, 2016) (internal citation omitted) (citing Syl. Pts. 2 & 6, Hinchman v. Gillette, 618 S.E.2d 387, 388-89 (W.Va. 2005)). In determining whether a certificate of merit fails to comply with the MPLA, "a court should ask whether a plaintiff has made a good faith attempt to comply with the pre-suit requirements of the MPLA." Butts v. Bekeley Medical Center, 2016 WL 11504761, at *3 (S.D. W.Va. July 20, 2016) (citing Earle, 2016 WL 3198396, at *5 and Hinchman, 618 S.E.2d at 395). In Hinchman, the court noted that dismissal

for failure to comply with the requirements of the MPLA was "a draconian remedy" but also held that a healthcare provider who finds the notice of claim or screening certificate to be insufficient may reply within thirty days with a request for a more definite screening certificate, as RGH did here. 618 S.E.2d at 395.

Dr. James' certificate of merit, though brief, appears to fulfill the dual statutory purposes. Dr. James indicated in his report that he reviewed various health records, the operation report, and a recording of a conversation between plaintiff and Dr. Lindley. Based on this information and his expertise as an obstetrician and gynecologist, he concluded that the case was with merit, thus serving the purpose of screening out frivolous claims. While the Supreme Court of Appeals has yet to clarify the level of particularity that the contents of the certificate must be made with to give notice of the claim, the certificate here appears sufficiently particularized to make RGH aware of the nature of the claim against it.

The dual statutory purposes are even more clearly fulfilled considering the detailed notice of claim, which plaintiff asks us to read in conjunction with the certificate of merit. The notice of claim lays out the theory of liability against RGH, in similar detail as it is pled in the complaint.

While there does not appear to be a case on point from the Supreme Court of Appeals authorizing the documents to be analyzed in conjunction, it would be in line with the Hinchman court's instruction to focus on fulfillment of the statutory purposes by considering both pre-suit documents together.

Moreover, even if the court were to find Dr. James' certificate of merit insufficient, RGH has not demonstrated that dismissal is appropriate here. As the Supreme Court of Appeals noted in Davis v. Mound View Health Care, Inc., the "pre-suit notice of claim and certificate of merit provisions are not intended to restrict or deny a citizen's access to our courts." 640 S.E.2d 91, 95 (W.Va. 2006) (citing Syl. pt. 2, in part, Hinchman, 618 S.E.2d 387); see also Westmoreland v. Vaidya, 664 S.E.2d 90, 99 (Starcher, J. concurring) ("Pre-suit notices and screening certificates of merit have some meritorious public policy goals, but these procedural humps should not be interpreted to restrict, delay, or deny citizens' access to the courts.").

The court notes that none of the cases relied upon by RGH found dismissal appropriate except where the plaintiff failed entirely to provide the pre-suit documents. See e.g., Faircloth, 835 S.E.2d 579; Cline v. Kresa-Reahl, 728 S.E.2d 87 (W.Va. 2012). Indeed, it would be the rare case where the

sufficiency of the pre-suit documents, actually provided, fall short of the standard that a plaintiff demonstrate "good faith and reasonable effort to further the statutory purposes," especially given the Supreme Court of Appeals stated aversion to dismissal on these grounds. Syl. pt. 6, Hinchman, 618 S.E.2d 387. Here, plaintiff's counsel provided the pre-suit documents and explained in the response letter plaintiff's position that the certificate of merit contained sufficient information to put RGH on notice of the claims against it. The court finds that this was a good faith and reasonable attempt to meet the requirements of the statute. Thus, dismissal based on failure to comply with the pre-suit requirements is unwarranted.

2. Failure to state a claim upon which relief can be granted

RGH argues principally in its motion to dismiss for failure to state a claim that it cannot be held liable for negligence because Dr. Lindley was not an employee or agent of RGH at the time of the surgery and plaintiff knew he was an outside physician. RGH further argues that it was not involved in the decision to remove plaintiff's uterus or the method of removal and had no duty under West Virginia law to intervene in the ongoing patient-physician relationship by warning the patient of the risks of the procedure. RGH cites to Cross v. Trapp, in which the Supreme Court of Appeals held that liability

will not ordinarily attach to a hospital where the treatment was performed by the patient's privately retained physician and where liability is based on failure to comply with the informed consent doctrine. 294 S.E.2d 446 (W.Va. 1982).

Plaintiff argues that Count II does not hinge solely on a theory of vicarious liability or informed consent and that the holding in Cross does not control this case.³ The court agrees. Among multiple theories of direct liability, plaintiff clearly pleads in Count II that RGH breached its standard of care by failing to ban morcellation in the hospital and by failing to equip the morcellator with a failsafe. Compl. ¶¶57-61. Cross held only that a hospital "will ordinarily not be held liable to the patient upon the consent issue." Id. at Syl. pt. 7. It did not create a blanket immunity for hospitals under all theories of negligence, and inasmuch as these are direct theories of liability, RGH presents no argument against holding it liable based on these alleged failures.

Count II of the complaint does also allege that RGH's failure to warn and ensure that plaintiff's decision was informed constituted negligence. Compl. ¶60. In relation to

³ Plaintiff also argues that Dr. Lindley may have been acting as the apparent agent of RGH. The court need not reach this argument presently for reasons infra.

these theories of liability, plaintiff argues that Cross does not control. Cross involved a doctor allegedly performing surgery on a patient while under anesthesia without the patient's consent to having that procedure performed. 294 S.E.2d 446. The court declined to find a general duty on the part of a host hospital to ensure that a patient consents to all procedures performed by the patient's retained physician, reasoning that obtaining informed consent for a medical procedure involves an "ongoing process" between physician and patient, and that requiring the hospital to intervene to ensure the patient's consent to the procedure could interfere with that process rather than facilitate it. Id. at 459. In making that finding, it contrasted the situation with one where the hospital is "placed upon notice of circumstances more extraordinary than those in [Cross]." Id. Here, plaintiff alleges that RGH was or should have been on notice as to the risks associated with morcellation and that RGH owned the allegedly unreasonably dangerous tool being used. Compl. ¶¶57, 58. A hospital may have a duty to ensure that patients undergoing procedures known to be unreasonably dangerous using unreasonably dangerous hospital equipment are aware of the risks associated with such procedures and equipment, and Cross is not to the contrary. Thus, plaintiff has stated a claim for negligence against RGH upon which relief can be granted.

3. Motion for summary judgment in the alternative

Finally, RGH attaches a form titled "Consent to Operation Treatment or Other Procedure," signed by plaintiff on May 8, 2018, which authorized Dr. Lindley to perform a robotic laparoscopic hysterectomy, including "possible morcellation." ECF No. 20-1. The form also indicates that among other risks of the surgery, cutting the "uterus into pieces in the abdomen can spread undiagnosed cancer (approximately 1 in 500)." Id. RGH contends in conclusory fashion that this proves that plaintiff received adequate counseling and medical advice on the benefits and risks of morcellation and thus, they should be dismissed from the action. No case law is cited for the proposition, and the court is unaware of any principle that such a consent form would relieve the hospital from its alleged duty to ban the use of the power morcellator in the hospital or from its alleged duty to equip the machine to mitigate the cancer-spreading risk.

The consent form might be relevant to whether RGH's duty to warn of the risks was discharged or whether RGH's failure to warn caused plaintiff's injuries, though neither argument is directly made in the motion. Whether plaintiff was adequately informed of the risks of morcellation or whether additional warnings may have changed plaintiff's decisionmaking will likely entail fact intensive inquiries and more

argumentation than what is presented. The form, particularly without the benefit of knowing its context, is not conclusive evidence on either issue and plaintiff is entitled to discovery to make its case on these issues. Conversion of the Rule 12(b) (6) motion into a Rule 56 motion is premature.

B. LiNA's Motion to Dismiss

Plaintiff has brought seven causes of action against LiNA, contending that LiNA is liable in strict liability for failure to warn (Count III) and design defect (Count IV), as well as liable for a breach of the implied warranty of merchantability and fitness (Count V), negligence (Count VI), violation of the West Virginia Consumer Credit and Protection Act (Count VII), and negligent misrepresentation (Count VIII). LiNA has moved to dismiss Counts III, IV, and V.

1. Design Defect

In Count IV of the complaint, plaintiff alleges that LiNA is strictly liable for the defective design of the Xcise model morcellator. Compl. ¶¶ 72-77. Plaintiff essentially offers two theories for defective design: (1) that the model was unreasonably dangerous because its benefits were outweighed by substantial, undisclosed risks when used as intended and (2) that there were safer alternative designs not carrying the same

risks, such as ones that include a "containment bag system" to capture errant malignant tissue. Id. at ¶74. Plaintiff also alleges that LiNA knew or should have known that medical providers would use and promote the use of the morcellator as though it were safe, that the applicable standard of care required LiNA to recall the morcellators or to equip them with a failsafe to prevent cancer spread, and that the defective design was the direct and proximate cause of plaintiff's injuries. Id. at ¶¶ 75-77.

In their motion to dismiss, LiNA argues that plaintiff cannot claim that nonuse of the product is the reasonable alternative design because that presupposes the inherent dangerousness of any power morcellator, a claim they contend sounds in medical malpractice, rather than products liability. ECF No. 21 at 7. Regarding inclusion of a surgical containment bag as a component to an alternative design, LiNA argues that containment bags were not recommended by experts and were not the industry norm at the time of manufacturing. Id. at 8. LiNA contends that plaintiff concedes this fact in her complaint. Id. at 7-8 (citing to Compl. ¶48). Finally, LiNA argues that plaintiff has failed to specifically plead that a reasonably prudent manufacturer would have designed the morcellator with

the containment bag system, and merely pleads that such a design was available at the time of marketing. Id. at 8.

In the seminal case of Morningstar v. Black & Decker Mfg. Co., the Supreme Court of Appeals explained that a products liability claim "may fall into three broad, and not necessarily mutually exclusive, categories: design defectiveness; structural [or manufacturing] defectiveness; and use defectiveness arising out of the lack of, or the inadequacy of, warnings, instructions, and labels." 253 S.E.2d 666, 682 (W.Va. 1979). The court defined defectiveness in three crucial syllabus points:

4. In this jurisdiction the general test for establishing strict liability in tort is whether the involved product is defective in the sense that it is not reasonably safe for its intended use. The standard of reasonable safeness is determined not by the particular manufacturer, but by what a reasonably prudent manufacturer's standards should have been at the time the product was made.

5. The term "unsafe" imparts a standard that the product is to be tested by what the reasonably prudent manufacturer would accomplish in regard to the safety of the product, having in mind the general state of the art of the manufacturing process, including design, labels and warnings, as it relates to economic costs, at the time the product was made.

6. The question of what is an intended use of a product carries with it the concept of all those uses a reasonably prudent person might make of the product, having in mind its characteristics, warnings and labels.

Id. at Syl. pts. 4-6. A design defect claim can be distilled into the following three elements: "(1) the design of the product at issue is defective in the sense that it renders the product not reasonably safe for its intended use, and (2) the defect proximately caused (3) the plaintiff's injury." Mullins v. Ethicon, 117 F.Supp.3d 810, 812-13 (S.D. W.Va. 2015). LiNA's motion to dismiss turns on whether plaintiff has pled sufficient facts to make out the first element, by showing the design is defective.

The Morningstar court adopted a "risk-utility test" for assessing product defectiveness, which "provides that a product's design is defective if its risks exceed its utility." Id. at 821; see also Goldsborough v. Bucyrus Intern., Inc., 2015 WL 3605404 at *11 (W.Va. June 9, 2015). The risk-utility test, as adopted by the Supreme Court of Appeals, consists of seven factors to determine whether a product's risks outweigh its utility. Id. (citing John W. Wade, On the Nature of Strict Tort Liability for Products, 44 Miss. L.J. 825, 829 (1973)). The seven factors are:

- (1) The usefulness and desirability of the product—its utility to the user and to the public as a whole.
- (2) The safety aspects of the product—the likelihood that it will cause injury, and the probable seriousness of the injury.
- (3) The availability of a substitute product which would meet the same need and not be as unsafe.
- (4) The manufacturer's ability to eliminate the unsafe character of

the product without impairing its usefulness or making it too expensive to maintain its utility. (5) The user's ability to avoid danger by the exercise of care in the use of the product. (6) The user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions. (7) The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.

Goldsborough, 2015 WL 3605404 at *11 n.8.

While LiNA is correct in observing that plaintiff did not explicitly plead that a reasonably prudent manufacturer would have designed the morcellator with a bag to capture tissue, plaintiff pled a multitude of facts which go to many of the factors above, and if proved, those facts would establish that the product may have been unreasonably dangerous. For example, plaintiff pleads that the bag technology was feasible at the time of manufacture and would have mitigated the unsafe character of the product, which goes to factor four, the manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.

LiNA argues as well that inclusion of containment bags was not the norm at the time of manufacturing and was not recommended by experts. They argue that allegations in the complaint at ¶48 concede that this is true. As plaintiff points

out in her response, this mischaracterizes the portion of the pleading cited in the motion. The paragraph merely cites to an academic article from 2017 for the proposition that a number of professional medical organizations had recommended use of a containment bag to prevent cancer spread. It does not follow, based on this citation, that the risks associated with morcellation were not well known prior to 2017.

Plaintiff argues as a factual matter that the risk of cancer spread from morcellation was well-known at the time of manufacture and cite to a number of patents for containment bags filed in the 1990s as evidence that the risks were well-known and presumably that the modification was feasible at the time of manufacture. Plaintiff further argues that even if the containment bags were not industry norms or recommended widely by experts, it would not be dispositive of product defectiveness under the Morningstar standard.

The court agrees with the latter argument, as the multi-factor test established in Morningstar is not amenable to resolution based on the absence of industry norms or expert recommendations alone. Moreover, plaintiff pled in her complaint that "[t]he surgical containment bag system and other preventative designs have been available since the early 1990s, long before the Xcise model morcellator was brought to market."

Compl. ¶49. The statement is plausible, and it is too early to assess its accuracy without the benefit of discovery on the matter. It is also too early to rule on the fact-intensive inquiry of defectiveness set out by Morningstar. Therefore, the motion to dismiss on Count IV is denied.

2. Failure to Warn

In Count III, plaintiff argues that LiNA is liable in strict liability for failing to warn plaintiff and the public at large for the risks associated with the Xcise model power morcellator. Specifically, the count alleges that LiNA failed to disclose the risk of cancer spread, failed to "adequately advise physicians to conduct pre-operative screenings to detect the presence of uterine cancer prior to morcellation procedures," failed to disclose the "rates at which laparoscopic power morcellators disseminate and/or upstage cancerous and non-cancerous fibroid tumors," and failed to disclose the possibility and need for additional procedures and treatments post-surgery, as well as other long-term health consequences compared to other forms of treatment for uterine fibroid removal. Compl. ¶ 70(a)-(d). Plaintiff alleges that these failures were the direct and proximate cause of plaintiff's injuries. Id. at ¶71.

LiNA primarily argues that the learned intermediary doctrine bars recovery in this case. The West Virginia legislature codified the learned intermediary doctrine in 2016, expressing its intention "to adopt and allow the development of a learned intermediary doctrine as a defense in cases based upon claims of inadequate warning or instruction for prescription drugs or medical devices." W. Va. Code. § 55-7-30(b). The statute provides that manufacturers or sellers of prescription medical devices will not be liable for a failure to warn unless:

(1) The manufacturer or seller of a prescription drug or medical device acted unreasonably in failing to provide reasonable instructions or warnings regarding foreseeable risks of harm to prescribing or other health care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; and

(2) Failure to provide reasonable instructions or warnings was a proximate cause of harm.

§ 55-7-30(a). As a result, LiNA argues that it had no duty to warn either plaintiff or the public at large of the alleged dangers and that any such duty would have been owed only to Dr. Lindley.

Plaintiff does not contest the applicability of the learned intermediary doctrine but instead argues that she has successfully pled that LiNA failed to meet its duty to warn Dr. Lindley. Indeed, plaintiff alleges in three separate paragraphs that LiNA failed to "adequately warn surgeons and hospitals of

the risk of morcellator use," that "the labeling was insufficient to adequately warn medical providers and patients of the significant risks of disseminating occult cancerous cells and the resulting likelihood of upstaging patients' cancer," and that LiNA "failed to adequately warn and inform medical providers" of the morcellator's risks. Compl. ¶¶50, 68, 70. While the court agrees with LiNA that the allegations in the complaint regarding the failure to warn plaintiff or the public at large do not demonstrate a breach of the relevant duty, the court finds that the cited allegations sufficiently allege LiNA's breach of the relevant duty to warn medical providers in this case and thus plaintiff has met the requirements of § 55-7-30(a)(1).

LiNA also argues that even if they breached their duty to warn the relevant health care providers, plaintiff cannot show that the breach was the cause of her injury. In particular, LiNA points to the allegation that Dr. Lindley did not even discuss the morcellation procedure with plaintiff. Compl. ¶35. LiNA argues that if it had provided adequate warnings, plaintiff would still not have had the opportunity to rely on those warnings if Dr. Lindley never discussed the procedure at all with her.

Nevertheless, as plaintiff points out, it may have been the absence of a proper warning accompanying the morcellator that caused Dr. Lindley's failure to discuss any of the procedure's risks with plaintiff. Further, the argument does not speak to plaintiff's allegation that adequate warnings might have led Dr. Lindley to conduct an alternative, safer course of treatment with plaintiff, such as by opting for a traditional vaginal hysterectomy or by performing a pre-operation cancer screening. See Compl. ¶70(c), (d).

In its reply brief, LiNA furthers its causation argument by pointing out that the complaint does not allege that Dr. Lindley relied on any other information from LiNA, or that he ever read any provided warnings on the product. Because plaintiff has not alleged Dr. Lindley relied on other warnings, LiNA argues, plaintiff is unable show that Dr. Lindley would have changed his behavior had additional warnings been added or existing warnings modified.

The reply brief is the first instance in which the existence of other warnings or information provided by LiNA is raised and plaintiff did not have the opportunity to respond to this argument. Nonetheless, Dr. Lindley's failure to heed other warnings by LiNA, if any were given, would be but one means of proving that the lack of warnings caused plaintiff's injury.

Plaintiff need not lay out at this time exactly how she intends to prove that additional warnings would have prevented her injury. At the pleadings stage, it suffices that the complaint alleges that "[b]ecause of the LiNA Medical Defendants' failure to adequately warn surgeons and hospitals of the risk of morcellator use. . . Plaintiff suffered avoidable bodily injury that may also significantly decrease her life expectancy." Compl. ¶50. Consequently, plaintiff has adequately pled both the breach of the duty to warn and proximate cause. Thus, the motion to dismiss Count III is denied.

3. Breach of Implied Warranty of Merchantability and Fitness

In Count V, plaintiff alleges that LiNA is a merchant with respect to the Xcise power morcellator, that the morcellator was sold with implied warranties of merchantability and fitness, that plaintiff relied on those implied warranties, that they were breached because the Xcise model was not fit for the ordinary purpose morcellators are used for, and as a direct and proximate result, plaintiff suffered damages. Compl. ¶¶78-82.

LiNA argues that the complaint is devoid of factual allegations and that plaintiff merely restates the elements of the cause of action for breach of the implied warranties. Plaintiff in response points out that this court has previously

held that "claims for strict liability and breach of the implied warranty of merchantability are essentially coextensive in products liability actions." See Keffer v. Wyeth, 791 F.Supp.2d 539, 545 (S.D. W.Va. 2011); accord Raab v. Smith & Nephew, Inc., 150 F.Supp.3d 671, 700 (S.D. W.Va. 2015). Thus, if the factual allegations in relation to Counts III and IV are sufficient to survive the motion to dismiss, then so too must the court find that the factual allegations in relation to Count V are sufficient.

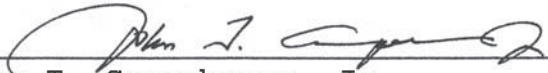
Inasmuch as the court has found Counts III and IV to be sufficiently pled for reasons outlined supra, the court finds that Count V is sufficiently pled.

IV. Conclusion

Accordingly, it is hereby ORDERED that RGH's motion to dismiss plaintiff's complaint, or in the alternative motion for summary judgment, and LiNA's motion to dismiss plaintiff's complaint be, and they hereby are, denied.

The Clerk is directed to transmit copies of this memorandum opinion and order to all counsel of record and any unrepresented parties.

ENTER: January 5, 2021



John T. Copenhaver, Jr.
Senior United States District Judge